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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,832	12/24/2003	Hiroyuki Komazawa	Q79195	1128
23373	23373 7590 10/18/2006		EXAMINER	
	MION, PLLC	MARX, IRENE		
2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 10/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)				
Office Action Summary		10/743,832	KOMAZAWA ET AL.				
		Examiner	Art Unit				
		Irene Marx	1651				
	The MAILING DATE of this communication app	ears on the cover sheet with the c	orrespondence address				
Period fo	• •						
WHIC - Exter after - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DATE of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. It period for reply is specified above, the maximum statutory period were to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tirr vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N.  nely filed  the mailing date of this communication.  D (35 U.S.C. § 133).				
Status							
1)⊠	Responsive to communication(s) filed on 18 Ju	<u>ıly 2006</u> .					
• —	This action is <b>FINAL</b> . 2b)⊠ This action is non-final.						
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
	closed in accordance with the practice under E	x parte Quayle, 1935 C.D. 11, 45	53 O.G. 213.				
Dispositi	on of Claims						
4)⊠	Claim(s) <u>1-18</u> is/are pending in the application.						
·	4a) Of the above claim(s) <u>3-18</u> is/are withdrawn from consideration.						
5)□	5) Claim(s) is/are allowed.						
6)⊠	Claim(s) <u>1 and 2</u> is/are rejected.						
•	Claim(s) is/are objected to.						
8)∐	Claim(s) are subject to restriction and/or	r election requirement.					
Applicati	ion Papers						
9)[	The specification is objected to by the Examine	r.					
10)	The drawing(s) filed on is/are: a) acce	epted or b) objected to by the E	Examiner.				
	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
11)	Replacement drawing sheet(s) including the correct The oath or declaration is objected to by the Ex						
Priority (	ınder 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:							
1.☐ Certified copies of the priority documents have been received.							
2. Certified copies of the priority documents have been received in Application No							
3. Copies of the certified copies of the priority documents have been received in this National Stage							
application from the International Bureau (PCT Rule 17.2(a)).							
* 5	See the attached detailed Office action for a list	of the certified copies not receive	∘d.				
Attachmen		" <b></b>					
	e of References Cited (PTO-892) te of Draftsperson's Patent Drawing Review (PTO-948)	4) Interview Summary Paper No(s)/Mail Da					
3) 🔯 Infon	mation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) or No(s)/Mail Date		Patent Application (PTO-152)				

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### **DETAILED ACTION**

The application should be reviewed for errors.

To facilitate processing of papers at the U.S. Patent and Trademark Office, it is recommended that the Application Serial Number be inserted on every page of claims and/or of amendments filed.

Applicant's election without traverse electing to prosecute the invention of Group I, claims 1-2 on 7/18/06 is acknowledged.

Claims 1-2 are being considered on the merits. Claims 3-18 are withdrawn from consideration as directed to a non-elected invention.

#### Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1 and 2 are rejected under 35 U.S.C. 101 because this claim reads on the organism per se which is found in nature and thus, is unpatentable to applicant. Consequently, the claim does not embody patentable subject matter as defined in 35 USC 101. See, e.g., American Wood v. Fiber Disintegrating Co., 90 U.S. 566 (1974); American Fruit Growers v. Brogdex Co., 283 U.S. 1 (1931); Funk Brothers Seed. Co. v. Kalo Innoculant Co.., 33 U.S. 127 (1948); Diamond v. Chakrabarty, 206 U.S.P.Q. 193 (1980).

It is suggested that applicant use the language "a biologically pure culture" in connection with the strain to identify a product that is not found in nature and to indicate the hand of man.

#### Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 2 is vague and indefinite in the use of parenthesis, since it is unclear whether the parenthetical material is or is not intended to be part of the claim. In addition, the designation LFF1 in this context does not clearly define a strain. The phrase "a strain of the same genus as the LFF1 strain is redundant, since the strain belongs to the genus *Thraustochytrium*.

Claim 2 is further vague and indefinite in the recitation of "a strain having fungological properties substantially identical to those of the LFF1 strain". It is unclear which properties are "fungological" or how similar the strain as claimed is intended to be as encompassed by "substantially identical". It is suggested that the language -- a strain having all of the identifying characteristics of the strain FERM BP-08568-- be substituted therefor.

## Claim Rejections - 35 USC § 112

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ a novel strain of *Thraustochytrium* to obtain a specific product. The written description of that strain and the method of isolating is insufficiently reproducible. Therefore, a deposit for patent purposes is required. The specification discloses at page 7 that *Thraustochytrium* LFF1 strain was deposited at National Institute of Advanced Industrial Science and Technology under Budapest Treaty conditions on December 10, 2003.

For compliance with the rule, it must be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent. MPEP 2403.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository and the complete taxonomic description.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Singh et al. (1996) or Singh et al. or Li et al. or Lewis et al. or Iida et al. or Bajpai et al. (1991) or Bajpai (2000).

The claims are directed to a *Thraustochytrium* capable of producing docosahexaenoic or a specific strain LFF1 or a strain having fungological properties substantially identical to those of the LFF1 strain".

Each of Singh et al. (1996) or Singh et al. or Li et al. or Lewis et al. or Iida et al. or Bajpai et al. (1991) or Bajpai (2000) discloses a *Thraustochytrium* strain that is capable of producing docosahexaenoic and which at least has fungological properties substantially identical to those of the LFF1 strain if it is not substantially identical to strain LFF1. See, e.g., respective abstracts or Lewis et al. Table 1.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Irene Marx
Primary Examiner
Art Unit 1651